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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,491	02/05/2002	Philip Kusk	8969-029	4096

7590 05/20/2003  
Pennic & Edmonds  
1667 K Street NW  
Washington, DC 20006

EXAMINER  
SWITZER, JULIET CAROLINE

ART UNIT PAPER NUMBER  
1634

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,491	<b>Applicant(s)</b> KUSK, PHILIP	
	<b>Examiner</b> Juliet C. Switzer	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-15, drawn a method of assessing an individual's predisposition to a selected calcification condition status. Further, Group 1 contains therein a multitude of inventions, wherein each separate invention is drawn to a method which uses a combination of one, two, three or four of the different recited genes. Even further still, the methods of group 1 encompass the examination of six different polymorphisms. If applicant selects group 1 for examination, applicant must select a **SINGLE COMBINATION** of genes and polymorphisms for examination, from all of the possible combinations required within group 1. For example, the single selected combination might be a method that requires determining the genotype of the promoter of the bone sialoprotein gene at position BSP-A1496G.

Group 2, claim(s) 16, 17, and 18, drawn to a DNA comprising a bone sialoprotein gene or a fragment thereof.

Group 3, claim(s) 16 and 19, drawn to a DNA comprising a matrix gla protein gene or a fragment thereof.

Group 4, claim(s) 16, 20, and 21, drawn to a DNA comprising an osteopontin gene or a fragment thereof.

Group 5, claim(s) 16 and 22, drawn to a DNA comprising an osteoprotegerin inhibitory factor gene or a fragment thereof.

Group 6, claim(s) 23, drawn to a method of osteoporosis therapy. Further, Group 2 contains therein a multitude of inventions, wherein each separate invention is drawn to a method which uses a combination of one, two, three or four of the different recited genes. Even further still, the methods of group 6 encompass the examination of six different polymorphisms. If applicant selects group 6 for examination, applicant must select a **SINGLE COMBINATION** of genes and polymorphisms for examination, from all of the possible combinations required within group

6. For example, the single selected combination might be a method that requires determining the genotype of the promoter of the bone sialoprotein gene at position BSP-A1496G.

Group 7, claim(s) 24, drawn to a method of atherosclerosis therapy. Further, Group 1 contains therein a multitude of inventions, wherein each separate invention is drawn to a method which uses a combination of one, two, three or four of the different recited genes. Even further still, the methods of group 7 encompass the examination of six different polymorphisms. If applicant selects group 7 for examination, applicant must select a **SINGLE COMBINATION** of genes and polymorphisms for examination, from all of the possible combinations required within group 7. For example, the single selected combination might be a method that requires determining the genotype of the promoter of the bone sialoprotein gene at position BSP-A1496G.

2. The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The methods and combinations within group 1, these combinations are joined by the fact that they are methods for assessing an individual's predisposition to a selected calcification condition status comprising genotyping the promoter of at least one gene. Such a method does not provide a special technical feature over the prior art, because such methods were known in the prior art, for example Grainger *et al.* (WO 97/28280) provide a method for assessing an individual's predisposition to osteoporosis by determining the genotype of the individual's TGF- $\beta$ 1 promoter.

4. The methods and combinations of group 1 are not joined by a special technical feature to the products of groups 2-5 because the products of groups 2-5 are not recited in or required for the methods of group 1. Furthermore, the products of groups 2-5 are sufficiently broad so as to encompass any primer or oligonucleotide that is a fragment of any one of the relevant genes and could be used for amplification of the gene promoter (claim 16). Each of the relevant genes herein were disclosed in the prior art (as taught in the specification at pages 6-7) and thus, such fragments are not a special technical feature over the prior art.

5. The methods of groups 6 and 7 are separate processes from group 1 and from one another. The methods are directed to different methods having different objectives and requiring different process steps. The methods of group 6 are directed towards treating osteoporosis while the methods of group 7 are directed towards treating arteriosclerosis.

6. A telephone call was made to Max Bachrach on 5/6/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Art Unit: 1634

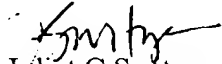
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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Juliet C Switzer  
Examiner  
Art Unit 1634

May 19, 2003

**JEHANNE SOUAYA**  
**PATENT EXAMINER**

  
5/19/03